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## PATENT APPLICATION

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	COHEN, Fredric Jay, et al.	)
Serial No.	:	FILED CONCURRENTLY HEREWITH	)
Filed	:	FILED CONCURRENTLY HEREWITH	)
For	:	METHODS OF PREVENTING BREAST CANCER	)
Docket No.	:	X-11057C	)

## **INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

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As a means of complying with the duty of disclosure, Applicants submit an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) for consideration by the Examiner.

As permitted by 37 C.F.R. §1.98(d), Applicants refer to application Serial Nos. 09/254,375, 09/368,688, and 09/931,159 filed March 29, 1999, August 5, 1999 and August 16, 2001, respectively for copies of the listed documents.

Since this Statement is being filed in accordance with 37 C.F.R. 1.97(b), Applicants submit that no additional fee is required.

Applicants request consideration of this information.

Respectfully submitted,

William R. Boudreaux Attorney for Applicants Registration No. 35,796

Phone: 317-276-0755

Eli Lilly and Company Patent Division/WRB P.O. Box 6288 Indianapolis, Indiana 46206-6288

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Sheet 1 of 2

FORM PTO 1449 (modified)	Atty. Docket No. X-11057C	Serial No FILED CONCURRENTLY HEREWITH			
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicants COHN, Fredric Jay, et al.				
	Filing Date FILED CONCURRENTLY HEREWITH	Group			

Examiner	Cite	Document Number	Publication	n Dote Ni	ne of Potentos on	Doggo C	olumne Lie-	
Initials*	No. 1	Number-Kind Code <sup>2</sup> (if know			Name of Patentee or Applicant of Cited Document		Pages, Columns, Lines Where Relevant Pages or Relevant Figures Appear	
	AA	US 4,418,068	11/29/1983	Jones				
	AB	US 4,656,187	04/07/1987	Black,	et al.			
	AC	US 5,478,847	12/26/1995	Draper				
	AD	US 5,604,248	02/18/1997	Bryant,	et al.			
	AE	US 5,472,962	12/05/1995	Koizun	ni, et al.		•	
· · · · · · · · · · · · · · · · · · ·	AF	US 5,821,254	10/13/1998	Sporn,	et al.			
	AG	US 5,075,321	12/24/1991	Schreit	per			
	<u>.</u>	FOR	EFIGN PATENT	C DOCUMENTS		<u> </u>		
			LEIGN PATENT		<u> </u>			
Examiner Initials*	Cite No. 1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4-</sup> Kind Code5 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lin Relevant Passages o Figures App	r Relevant	T <sup>6</sup>	
		Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -	Publication Date	Name of Patentee or Applicant of Cited	Pages, Columns, Lir Relevant Passages o	r Relevant	76	
	No. 1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code5 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lir Relevant Passages o	r Relevant	T <sup>6</sup>	
	No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> Kind Code5 (if known)  EP 680 758 A1	Publication Date MM-DD-YYYY 04/05/1995	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lir Relevant Passages o	r Relevant	T <sup>6</sup>	
	BA BB	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code5 (if known)  EP 680 758 A1  EP 652 004 A1	Publication Date MM-DD-YYYY 04/05/1995 10/13/1994	Name of Patentee or Applicant of Cited Document  EPO  EPO	Pages, Columns, Lir Relevant Passages o	r Relevant	T <sup>6</sup>	
	BA BB BC	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code5 (if known)  EP 680 758 A1  EP 652 004 A1  EP 674 903 A1	Publication Date MM-DD-YYYY 04/05/1995 10/13/1994 02/10/1995	Name of Patentee or Applicant of Cited Document  EPO  EPO  EPO	Pages, Columns, Lir Relevant Passages o	r Relevant	T <sup>6</sup>	
	BA BB BC BD	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code5 (if known)  EP 680 758 A1  EP 652 004 A1  EP 674 903 A1  EP 0 839 532 A1	Publication Date MM-DD-YYYY 04/05/1995 10/13/1994 02/10/1995 10/29/1997	Name of Patentee or Applicant of Cited Document  EPO  EPO  EPO  EPO	Pages, Columns, Lir Relevant Passages o	r Relevant	T <sup>6</sup>	
	BA BB BC BD BE	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code5 (if known)  EP 680 758 A1  EP 652 004 A1  EP 674 903 A1  EP 0 839 532 A1  EP 0 659 419 A1	Publication Date MM-DD-YYYY 04/05/1995 10/13/1994 02/10/1995 10/29/1997 12/19/1994	Name of Patentee or Applicant of Cited Document  EPO  EPO  EPO  EPO  EPO  EPO	Pages, Columns, Lir Relevant Passages o	r Relevant	T <sup>6</sup>	

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	Filing Date FILED CONCURRENTLY HEREWITH	Group			

Examiner Initials*	Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher,							
	CA	Jordan V. Craig: "Alternate Antiestrogens and Approaches to the Prevention of Breast Cancer"; Journal of Cellular Biochemistry, 58:S.22, pp. 51-57 (1995)	<del>-</del> ·					
<del></del>	СВ	Anzano, M. A., et al.: "Chemoprevention of Mammary Carcinogenesis in the Rat: Combined Use of Raloxifene and 9-Cis-Retinoic Acid"; Journal of the National Cancer Institute, 88:2, pp. 123-125 (1996)	,					
	CC .	"First Phase III Results with Raloxifene": Database File 129, Dialog Information Services, 00540210, June 13, 1997						
	CD	"Market Analysis from Decision Resources: Breast Cancer"; Database File 187, Dialog Information Services, 1249, April 1, 1996						
	CE	"National Chemopreventive Agents in Experimental Mammary Carcinogenesis"; Anzano, Crisp Data Base National Institute of Health, CRISP-96-9057 (1995)						
	CF	Anzano: Caplus Abstract Accession Number 1996:122169 and J. National Cancer Institute (1996); 88(2), pp. 123-125						
	CG	Jordan: Biosis Abstract Accession Number 95:496471 and Breast Cancer Research and Treatment (1995); 36(3), pp. 267-285						
	СН	Jones: Caplus Abstract Accession Number 1984:448784 and J. Med. Chem. (1984); 27(8), pp. 1057-1066						
	CI	Clemens: Caplus Abstract Accession Number 1993:432846 and Life Science (1983); 32(25), pp. 2869-75						
	CJ	Lerner, L. J., et al.: "Development of Antiestrogens and Their Use in Breast Cancer: Eighth Cain Memorial Award Lecture"; Cancer Research, 50, pp. 4177-4189 (1990)						
	CK Cummings, S. R., et al.: "The Effect of Raloxifene on Risk of Breast Cancer in Postmenopausal Women - Results from the MORE Randomized Trial"; JAMA, pp. 2189 2197 and p. 2124, Vol. 281, No. 23 (June 16, 1999)							
	CL Cauley, J. A., et al.: Continued Breast Cancer Risk Reduction in Postmenopausal Women Treated with Raloxifene: 4-year Results from the MORE Trial"; Breast Cancer Research and Treatment, 65: pp. 125-134 (2001)							
CM Buzdar, A. U., et al., "Phase II Evaluation of LY156758 in Metastatic Breast Cancer"; Oncology, 45: pp. 344-345 (1988)								
Examiner	ĺ	Date Considered						

FEXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. Burden Hours Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer. U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.